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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,759	04/18/2000	ERIC VIVIER	A33131-PCT-U	9965

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,759	VIVIER ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 58-83 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 58-83 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634, and has been docketed to Primary Examiner Bradley L. Sisson.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 58-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus,

an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. For convenience, claims 58-61, the only independent claims, are reproduced below.

58. (currently amended) An *in vitro* method for identifying the repertoire of NKR inhibitory immunoreceptors within a subject wherein said immunoreceptors are selected from the group consisting of p58.1, p58.2, p70.INH, p140.NH, NKG2A and NKG2B receptors, these immunoreceptors being designated hereinafter target receptors, comprising:

(i) contacting a nucleic acid sample derived from said subject with at least one pair of oligonucleotides, one being designated a 3' oligonucleotide and the other a 5' oligonucleotide, and wherein the 3' and 5' oligonucleotides hybridize in a buffer comprising 20 mM Tris-HCl, pH 8.4; 50 mM KCl; 2.5 mM $MgCl_2$ at a temperature of between 50°C and 65°C, to a nucleic acid encoding a target receptor, but do not hybridize, under the same hybridization conditions, with a NKR activatory immunoreceptor counterpart and wherein;

(a) the 5' oligonucleotide comprises the sequence of SEQ ID No.1, and at least one 3' oligonucleotide selected from the

group of 3' oligonucleotides comprising the sequence of SEQ ID No. 5, No. 2, No. 6 or No. 7; or

(b) the 5' oligonucleotide comprises the sequence of SEQ ID No. 4 and at least one 3' oligonucleotide selected from the group of 3' oligonucleotide comprising the sequence of SEQ ID No. 5, No. 2, No. 6 or No. 7, or a sequence which is derived therefrom; or

(c) the 5' oligonucleotide comprises the sequence of SEQ ID No. 9, or a sequence which is derived therefrom, and at least one 3' oligonucleotide selected from the group of 3' oligonucleotides comprising the sequence SEQ ID No. 5, No. 2, No. 6 & or No. 7, or a sequence which is derived therefrom; or

(d) at least one 5' oligonucleotide comprising the sequence of SEQ ID No. 10, No. 11, No. 12 or No. 13 is selected from the group consisting of a 3' oligonucleotide comprising the sequence SEQ ID No. 14, or a sequence which is derived therefrom; and

(ii) detecting hybridization between the nucleic acid encoding the

NKR inhibitory immunoreceptor and the 3' and 5' oligonucleotide pair(s), wherein detection of hybridization between the nucleic acid encoding the NKR inhibitory immunoreceptor and the 3' and 5' oligonucleotide pair(s)identifies the repetoire of NKR inhibitory receptors.

~~7~~ 58. (Previously presented) An *in vitro* method for identifying the repertoire of NKR activatory immunoreceptors within a subject wherein said immunoreceptors are selected from the group consisting of p50.1, p50.2, p70.ACT, p140.ACT, NKG2C, NKG2D, NKG2E and NKG2F, these immunoreceptors being designated hereinafter target receptors, comprising:

(i) contacting a nucleic acid sample derived from said subject with at least one pair of oligonucleotides, one being designated a 3' oligonucleotide and the other a 5' oligonucleotide, wherein the 3' and 5' oligonucleotides hybridize in a buffer comprising 20 mM Tris-HCl, pH 8.4; 50 mM KCl; 2.5 mM $MgCl_2$ at a temperature of between 50°C and 65°C, to a nucleic acid encoding a target receptor, but do not hybridize, under the same hybridization conditions, with a NKR inhibitory immunoreceptor counterpart and wherein;

(a) the 3' oligonucleotide of a said 3' and 5' oligonucleotide pair, used for determining the repertoire of NKR activatory immunoreceptors, is capable, under the same said hybridization conditions, of hybridizing to a nucleic acid encoding KAR target receptor wherein said nucleic acid encodes the amino acid sequence Lys Ile Pro Phe Thr Ile (K I P F T I) or Lys Leu Pro Phe Thr Ile (K L P F T I) (SEQ ID No. 26 or 27); or

(b) the 5' oligonucleotide comprises the sequence of SEQ ID No. 1 and a 3' oligonucleotide comprising the sequence of SEQ ID No. 3;or

(c) the 5' oligonucleotide comprises the sequence of SEQ ID No. 8 and a 3' oligonucleotide comprising the sequence of SEQ ID No. 3; or

(d) the 5' oligonucleotide comprising the sequence of SEQ ID No. 9 and a 3' oligonucleotide comprising the sequence SEQ ID No. 3; or

(e) the 5' oligonucleotide comprises the sequence of SEQ ID No. 15 and a 3' oligonucleotide comprising the sequence SEQ ID No.13; and

(ii) detecting hybridization between the nucleic acid encoding the NKR activatory immunoreceptor and the 3' and 5' oligonucleotide pair(s),

wherein detection of hybridization between the nucleic acid encoding the NKR activatory immunoreceptor and the 3' and 5' oligonucleotide pair(s)identifies the repetoire of NKR activatory receptors.

60. (Previously presented) An *in vitro* method for identifying the repertoire of NKR inhibitory immunoreceptors within a subject wherein said immunoreceptors are selected from the group consisting of p58.1, p58.2, p70.INH, p140.NH, NKG2A and NKG2B receptors, these immunoreceptors being designated hereinafter target receptors, comprising:

(i) contacting a nucleic acid sample derived from said subject with at least one pair of oligonucleotides, one being designated a 3' oligonucleotide and the other a 5' oligonucleotide, and wherein the 3' and 5' oligonucleotides hybridize in a buffer comprising 20 mM Tris-HCl, pH 8.4; 50 mM KCl; 2.5 mM $MgCl_2$ at a temperature of between 50°C and 65°C, to a nucleic acid encoding a target receptor, but do not hybridize, under the same hybridization conditions, with a NKR activatory immunoreceptor counterpart

and wherein said 3' and 5' oligonucleotide pairs are selected from the group consisting of:

(a) a 5' oligonucleotide comprising the sequence of SEQ ID No. 16 and a 3' oligonucleotide comprising the sequence SEQ ID No. 17;

(b) a 5' oligonucleotide comprising the sequence of SEQ ID No. 18 and a 3' oligonucleotide comprising the sequence SEQ ID No. 17;

(c) a 5' oligonucleotide comprising the sequence of SEQ ID No. 19 and a 3' oligonucleotide comprising the sequence SEQ ID No. 17; and

(d) a 5' oligonucleotide comprising the sequence of SEQ ID No. 20 and a 3' oligonucleotide comprising the sequence SEQ ID No. 21; and

(ii) detecting hybridization between the nucleic acid encoding the NKR inhibitory immunoreceptor and the 3' and 5' oligonucleotide pair(s),

wherein detection of hybridization between the nucleic acid encoding the NKR inhibitory immunoreceptor and the 3' and 5' oligonucleotide pair(s)identifies the repetoire of NKR inhibitory receptors.

61. (Previously presented) An *in vitro* method for identifying the repertoire of NKR activatory immunoreceptors within a subject wherein said immunoreceptors are selected from the group consisting of p50.1, p50.2, p70.ACT, p140.ACT, NKG2C, NKG2D, NKG2E and NKG2F, these immunoreceptors being designated hereinafter target receptors, comprising:

(i) contacting a nucleic acid sample derived from said subject with at least one pair of oligonucleotides, one being designated a 3' oligonucleotide and the other a 5' oligonucleotide, wherein the 3' and 5' oligonucleotides hybridize in a buffer comprising 20 mM Tris-HCl, pH 8.4; 50 mM KCl; 2.5 mM $MgCl_2$ at a temperature of between 50°C and 65°C, to a nucleic acid encoding a target receptor, but do not hybridize, under the same hybridization conditions, with a NKR inhibitory immunoreceptor counterpart and wherein said 3' and 5' oligonucleotide pairs are selected from the group consisting of:

(a) a 5' oligonucleotide comprising the sequence of SEQ ID No. 16 and a 3' oligonucleotide comprising the sequence SEQ ID No. 17;

(b) a 5' oligonucleotide comprising the sequence of SEQ ID No. 18 and a 3' oligonucleotide comprising the sequence SEQ ID No. 17;

(c) a 5' oligonucleotide comprising the sequence of SEQ ID No. 19 and a 3' oligonucleotide comprising the sequence SEQ ID No. 17; and

(d) a 5' oligonucleotide comprising the sequence of SEQ ID No. 20 and a 3' oligonucleotide comprising the sequence SEQ ID No. 21; and

(ii) detecting hybridization between the nucleic acid encoding the NKR activatory immunoreceptor and the 3' and 5' oligonucleotide pair(s),

wherein detection of hybridization between the nucleic acid encoding the NKR activatory immunoreceptor and the 3' and 5' oligonucleotide pair(s)identifies the repetoire of NKR activatory receptors.

5. For purposes of examination, the claims have been interpreted as encompassing immunoreceptors p58.1, p58.2, p70.INH, p140.NH, NGG2A, and NKG2B receptors as found in any life form. Said methods have also been interpreted as encompassing the use of virtually any oligonucleotide as a primer, be it for the 3' or 5' position. Such breadth of interpretation is based on the recitation "or a sequence which is derived therefrom" (claim 58). Said claims 58-83 have also been interpreted as encompassing simultaneous identification of said repertoire in a virtually infinite number of samples, wherein said samples can range in heterogeneity, and content for any given target nucleic acid, and wherein said identification of each and every repertoire is conducted with a sample that is either bound or in solution, where no label is used. In those instances where a label is used, the claimed methods have been interpreted as encompassing performing said identification when unincorporated label is not removed from incorporated label.

6. As presently worded, one is to have "oligonucleotides" (probes) hybridize to nucleic acid that encodes any of immunoreceptors p58.1, p58.2, p70.INH, p140.NH, NGG2A, and NKG2B, but does not hybridize with any nucleic acid that encodes a "NKR activatory immunoreceptor." It is noted with particularity that the names "p58.1, p58.2, p70.INH, p140.NH, NGG2A, and NKG2B " are of proteins, and that the specification does not teach the amino acid sequence of each of these proteins, or equivalents as found in any life form, nor does the specification teach the nucleotide residue sequence is for same. Clearly, knowing the target nucleic acid sequence is critical to practicing a hybridization reaction, yet the specification does not disclose these essential starting materials and as such, applicant has not provided an adequate written description f the reagents used in the method, including oligonucleotides that are to somehow be derived.

7. Similarly, the specification has not provided an adequate written description of any and all nucleic acids that encode a "NKR activatory immunoreceptor." Applicant has indicated how unnamed proteins are to function (i.e., NKR activatory immunoreceptor), however, such language does not provide an adequate written description of the nucleic acids that the oligonucleotides are not to hybridize to.

8. Page 5, last line, bridging to page 6 of the specification states:

> The invention provides, for the first time, means which make it possible to document, routinely in a medical or veterinary context, NKR and/or NKR counterpart repertoires, so as to be able to rapidly and effectively analyse physiological and pathological situations linked to these repertoires.

A review of the specification finds but two examples. Example 1, pages 17-22, describes the isolation of RNA from "cloned human NK cells phenotyped $p50.2^{+}$ and/or $p58.2^{+}$", the selection

of primes and conducting polymerase chain reaction. Example 2, pages 22-24, describes conducting PCR on DNA isolated from "a population of $p50.2^+$ transgenic mouse splenocytes." None of these example, or any other portion of the specification has been found to provide an adequate written description of how the detection of any one or combination of nucleic acid sequences encoding any portion of immunoreceptors p58.1, p58.2, p70.INH, p140.NH, NGG2A, and NKG2B is to then be extrapolated so that a skilled artisan can a) used to predict or to monitor the acceptance or rejection, by a subject, of cells, tissue or organ which are genetically different (claim 62); b) used to predict or to monitor the safety or the pathogenicity (GVH), or a subject, of a graft or transplant, of cells, tissue or organ which are genetically different (claim 63); c) predict or monitor a subject of a GVL-type effect on the part of cells, tissue, or organ which are genetically different (claim 64); d) used to determine the state of activation of NK and/or T cells within a subject (claim 65); e) used to screen for compositions which are used to reduced the symptoms associated with infectious autoimmune or proliferation disorders (claim 67); f) used to document the genotypic repertoire of KIR immunoreceptors (claims 77 and 78); and/or g) used to document the expression repertoire of KAR immunoreceptors (claims 79 and 80).

9. In accordance with claim 70, the oligonucleotides are coupled to a marker, which, is further defined a being "a fluorescent marker" or "a radioactive marker" (claims 71 and 72, respectively). A review of the specification, and especially the examples fails to find where any oligonucleotide was coupled to any marker, be it fluorescent, or radioactive. As seen in the two examples, the oligonucleotides served as primers in PCR and that an aliquot of the reaction mixture was electrophoresed on a 2% agarose gel, and were subsequently detected through the

use of specific antibodies. Clearly, the detection of amplification products through immunobinding does not provide an adequate written description of using labeled primers, and said description does not reasonably suggest that applicant had possession of the invention at the time of filing.

10. In accordance with claims 73-75, one is to perform polymerase chain reaction (PCR). A review of the disclosure, however, clearly shows that PCR was not conducted under the recited hybridization conditions. For convenience, page 20 is reproduced below in pertinent part.

> 3. Amplification by the polymerase chain reaction after enzymatic reverse transcription (RT-PCR)
>
> 5 µg of total RNA are transcribed into cDNA by incubating with a reverse transcriptase (RT) with the aid of the First Strand DNA-Ready to go kit (Pharmacia). 10 µl of cDNA out of the 33 µl obtained are brought into contact with oligonucleotide pairs C and D which serve, in this case, as primers (cf. Table 1): 10 µl of RT-derived product; 10X PCR buffer: 10 µl; $MgCl_2$ 50 mM; dXTP 10 mM; 3' oligonucleotide at 10 µM: 5 µl; 5' oligonucleotide 10 µM: 5 µl; Taq polymerase: 0.5 µl; H_2O: qs 100 µl. The PCR amplification (DNA engine PTC 200, MJ Research, Massachusetts) is carried out according to the following steps:
>
> - step No. 1 (initial denaturation): 5 min at 94°C,
> - step No. 2: 35 cycles comprising
>   a) denaturation 1 min at 94°C
>   b) annealing 1 min at 55°C for the oligonucleotide pair C and 50°C for the oligonucleotide pair D,
>   c) extension 1 min at 72°C,
> - step No. 3: (final extension):
>   1 min at 72°C.

The above disclosure does not reasonably suggest or adequately describe conducting PCR "wherein the 3' and 5' oligonucleotides hybridize in a buffer comprising 20 mM Tris-HCl, pH 8.4; 50 mM KCI; 2.5 mM $MgCl_2$ at a temperature of between 50°C and 65°C."

In view of the above remarks, it appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

11. The specification has not been found to provide an adequate written description of every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Accordingly, and in the absence of convincing evidence to the contrary, claims 58-83 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

12. Claims 58-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

13. It is well settled that one cannot enable that which they do not yet possess. As set forth above, the specification does not provide an adequate written description of the invention so as to reasonably suggest that applicant was in possession of the invention at the time of filing. Accordingly, claims 58-83 are not enabled by the specification.

In accordance with claim 58 one is to contact a target sequence with oligonucleotides that bind to one sequence but not another where defined conditions are used as a standard. The specification, however, does not teach what the nucleotide sequences of the target and excluded non-target sequences are, but rather, teaches the names of the proteins, or of the functionality of the proteins. Additionally, the specification does not set forth a reproducible procedure whereby

information derived from an oligonucleotide hybridizing to any one or combination of nucleic acid sequences encoding any portion of immunoreceptors p58.1, p58.2, p70.INH, p140.NH, NGG2A, and NKG2B is to then be extrapolated so that a skilled artisan can a) used to predict or to monitor the acceptance or rejection, by a subject, of cells, tissue or organ which are genetically different (claim 62); b) used to predict or to monitor the safety or the pathogenicity (GVH), or a subject, of a graft or transplant, of cells, tissue or organ which are genetically different (claim 63); c) predict or monitor a subject of a GVL-type effect on the part of cells, tissue, or organ which are genetically different (claim 64); d) used to determine the state of activation of NK and/or T cells within a subject (claim 65); e) used to screen for compositions which are used to reduced the symptoms associated with infectious autoimmune or proliferation disorders (claim 67); f) used to document the genotypic repertoire of KIR immunoreceptors (claims 77 and 78); and/or g) used to document the expression repertoire of KAR immunoreceptors (claims 79 and 80). The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing

> out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

14. In view o the broad scope of the claims an the limited disclosure provided, claims 58-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 62-67 and 77-80 are provides for the use of a method, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

17. Claims 62-67 and 77-80 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition

of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
13 April 2004